October 17, 2020

Sara Pautasso, PhD
Genetrack Biolabs, Inc.
180-4616 25th Avenue NE
Seattle, WA 98105

Re: EUA201469/S001
Trade/Device Name: Genetrack SARS-CoV-2 Molecular Assay
Dated: October 7, 2020
Received: October 7, 2020

Dear Dr. Pautasso:

This is to notify you that your request to update the EUA for the Genetrack SARS-CoV-2 Molecular Assay to include winter shipping stability study results to support specimen stability claims for the Vo' COVID-19 Test Home Collection Kit, is granted. Upon review, we concur that the data and information submitted in EUA201469/S001 supports the requested update for use with the Genetrack SARS-CoV-2 Molecular Assay. FDA has also updated the the SOP and EUA Summary to reflect recent policy. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Genetrack SARS-CoV-2 Molecular Assay issued on September 25, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health